Guidant Pulsar™/Pulsar Max™
INFORMATION FOR USE

Table of Contents

This chapter includes the following information associated with the PULSAR/PULSAR Max pacemakers.

Device Description

PULSAR/PULSAR Max PACEMAKERS

The PULSAR™/PULSAR Max™ (hereinafter referred to as PULSAR) pacemakers are multi-programmable pacemakers from Guidant. The family consists of both dual-chamber and single-chamber models, many offering adaptive-rate therapy (DR and SR models) and providing various levels of therapeutic and diagnostic functionality. The pacemakers feature IS-1 compatible connectors that accept both IS-1 and 3.2mm leads. Refer to Appendix A for information about the features of each model.

Two sensors are available with the PULSAR/PULSAR Max adaptive-rate models: minute ventilation detection and an accelerometer (motion sensor). These sensors adapt the pacing rate to the patient's changing metabolic demand. Minute ventilation responds to changes in respiration, and the accelerometer responds to patient activity (motion). PULSAR adaptive-rate models can use either the accelerometer or MV sensor; PULSAR Max models offer a blend of both accelerometer and minute ventilation. Refer to Chapter 3 – Technical Information for a detailed description of the sensors.

Refer to Appendix A for a complete list of available models.

Model 2890 SOFTWARE APPLICATION

The PULSAR/PULSAR Max pacemaker family can be interrogated and programmed using the Model 2901 Programmer/Recorder/Monitor (PRM) equipped with the Model 2890 CONSULT software. This allows you to view and change all programmed parameters to optimize the therapy, and to access the diagnostic information stored in the pacemaker.

PROGRAMMER / RECORDER / MONITORS

Guidant PRMs communicate with the pacemakers by means of radio frequency telemetry. The PRM provides simultaneous real-time ECG and telemetered signals and generates reports that detail pacemaker function, patient data, and test results. For more information, refer to the Operator's Manual for the Model 2901 PRM.

Indications and Usage

Guidant PULSAR series pacemakers are indicated for the following:

- Symptomatic paroxysmal or permanent second or third-degree AV block
- Symptomatic bilateral bundle branch block
- Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders (eg, sinus bradycardia, sinus arrest, sinoatrial [SA] block)
- Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias
- Neurovascular (vasovagal) syndromes or hypersensitive carotid sinus syndromes

Adaptive-rate pacing is indicated for patients who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity.

The Pulsar series pacemakers' dual chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of the following:

- Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block
- VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm
- Low cardiac output or congestive heart failure secondary to bradycardia

Contraindications

Guidant Pulsar pacemakers are contraindicated for the following applications:

- Patients with unipolar pacing leads or in MV mode with an implanted cardioverter-defibrillator (ICD), because it may cause unwanted delivery or inhibition of ICD therapy.
- MV mode in patients with unipolar ventricular leads.
- Single-chamber atrial pacing in patients with impaired AV nodal conduction.
- Atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing.
- Dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias.
- Asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms.

Warnings and Precautions

Minute Ventilation Sensor Calibration at Implant

WARNING: Inappropriate sustained high-rate pacing occurred in the clinical study in 5 out of 130 patients with MV ON, 4 to 14 days after implant. If sustained high rate pacing could be of concern, consider programming:

- **a reduced maximum sensor rate; or**
- **MV PASSIVE.**

These programming recommendations are intended to assure that MV calibration is evaluated, and if necessary, recalibrated (4-ON) when the patient and pacing system have stabilized post-implant. Continued monitoring of the MV sensor performance should be performed at all follow-up visits until implant stabilization has occurred (see MV Initialization section of WARNINGS and PRECAUTIONS for details of evaluation and correction of inappropriate high rate pacing).

Clinical Considerations

- In devices with the Safety Switch programmed to ON, the lead polarity will revert to unipolar in the presence of a lead impedance of < 100 Ω or > 2500 Ω. Unipolar pacing is contraindicated for patients with an ICD.
- STAT Pace will initiate unipolar pacing, which is contraindicated for patients with an ICD.

- Adaptive-rate pacing should be used with care in patients unable to tolerate increased pacing rates.
- Adaptive-rate modes based completely or in part on minute ventilation might be inappropriate for patients who can achieve respiratory cycles shorter than one second (greater than 60 breaths per minute). Higher respiratory rates attenuate the impedance signal, which diminishes the MV rate response (ie, the pacing rate will drop toward the programmed basic rate).
- Slow retrograde conduction combined with a short PVARP might induce pacemaker-mediated tachycardia.

Adaptive-rate modes based completely or in part on minute ventilation should not be used for the following patients:

- those implanted with an ICD.
- those with unipolar ventricular leads, because a bipolar lead is required for minute ventilation detection.
- those with epicardial ventricular leads, because minute ventilation measurement has only been tested with a bipolar transvenous lead.
- those using a mechanical ventilator, because use of the ventilator might result in an inappropriate MV sensor-driven rate.

Sterilization, Storage, and Handling

- **Do not freeze.** The recommended storage temperature range is 0 to 50°C(32–122°F). Exposure to temperatures outside this range may adversely affect pacemaker operation. **Extremely** low temperatures (below –20°C) could result in permanent memory loss. If this occurs, as indicated by a programmer error message, return the device to Guidant for inspection.
- FOR SINGLE USE ONLY—DO NOT RESTERILIZE DEVICES. Return the unimplanted device to Guidant.
- Do not implant a pacemaker if any of the following conditions apply:
  - If a Guidant pacemaker is dropped onto a hard surface. Return the device to Guidant for inspection.
  - If the "USE BEFORE" date that is printed on the packaging has passed, because this can adversely affect pacemaker longevity or sterility. **If a pacemaker with an expired "USE BEFORE" date is implanted, the pacemaker warranty is void.**
  - If the storage package has been pierced or altered, because this could have rendered it nonsterile.

Lead Evaluation and Connection

- **Pacing and sensing safety margins.** Consider lead maturation when choosing pacing amplitudes, pacing pulse widths, and sensing levels.
  - Acute pacing thresholds greater than 1 V or 2 mA or chronic pacing thresholds greater than 3 V or 6 mA can result in loss of capture be-cause thresholds increase after implantation.
  - R-wave amplitude less than 5 mV or P-wave amplitude less than 2 mV can result in undersensing because sensed amplitude decreases after implantation.
- **Line-powered equipment.** Exercise extreme caution if testing leads using line-powered equipment, because leakage current exceeding 10 mA can induce ventricular fibrillation.

- **Verifying setscrews**. Do not insert a lead into the pacemaker connector without first visually verifying that the setscrews are sufficiently retracted to allow insertion.
- **Pacemaker/lead compatability**. Prior to implanting this pacemaker, verify lead/pacemaker compatibility with Guidant technical services. If using an IS-1 or 3.2-mm unipolar lead not manufactured by Guidant with the PULSAR/PULSAR Max pacemakers, be sure the lead has an anode terminal protector to permit tightening of the proximal setscrew. All Guidant IS-1 and 3.2-mm leads have this protector.
- **Proper programming of the lead configuration.** If the lead configuration is programmed to bipolar when a unipolar lead is implanted, pacing will not occur.

Implantation

- **Implanting a replacement pacemaker in a subcutaneous pocket that previously housed a larger device** may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Flooding the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.
- **Defibrillation causing a power surge exceeding 360 watt-seconds** can damage the pacemaker system.

Programming and Pacemaker Operation

- **Use only a Guidant Programmer/Recorder/Monitor (PRM) and the Model 2890 CONSULT software application** to communicate with the PULSAR/ PULSAR Max pacemaker.
- **Telemetry communication can be interrupted by electrical noise, thus preventing improper interrogation or programming**. If the message window appears indicating that the wand is out of range or there is telemetry noise, move the programmer away from such electrical devices as electrosurgical and monitoring equipment and ensure that the wand cord and cables are not crossing one another. Telemetry communication will resume when the noise source is removed. The message window also has a Cancel button that, when selected, will stop the interrogation.
- **A pacemaker programmed to STAT pacing, if not reprogrammed, will continue to pace in SSI mode at the high-energy STAT values**. Reprogram the pacemaker to other parameter settings for alternative patient therapies or to extend pacemaker longevity.
- **Adaptive-rate pacing is not limited by refractory periods**. A long refractor period programmed in combination with a high MSR can result in asynchronous pacing during refractory periods, since the combination can cause a very small sensing window or none at all. Use dynamic AV delay or dynamic PVARP to optimize sensing windows.
- **If the Amplitude is OFF during temporary programming, the pacemaker will not pace.** Pacing with the permanently programmed parameters can be restored by breaking the telemetry link or by selecting the Cancel button on the "Temporary Parameters now in use" dialogue window.

MV Initialization

- In some patients MV Initialization will need to be repeated by performing the 4-ON initialization procedure. Factors affecting the MV baseline included lead maturation

effects, air entrapment in the pocket, pacemaker motion due to inadequate suturing, and other patient complications (eg, pneumothorax).

- A 4-ON initialization should be performed if the pacemaker is removed from the pocket following implant, such as during a lead repositioning procedure.
- A 4-ON initialization should be performed to establish a new MV baseline if one of the following conditions is noted during MV sensor evaluation:
  - Failure to achieve a significant sensor-indicated response with the MV Response Factor set to level 16
  - Observed maximum or elevated sensor-indicated rates with the MV response factor set to level 2

Environmental and Medical Therapy Hazards

Patients should be directed to avoid devices which generate a strong electric or magnetic interference (EMI). If the pulse generator inhibits or reverts to asynchronous operation at the programmed pacing rate or at the magnet rate while in the presence of the EMI, moving away from the source or turning it off will usually allow the pulse generator to return to its normal mode of operation.

Hospital and Medical Environments
Confirm pacemaker operation after any of the following medical procedures.

- **Mechanical ventilators** may cause an inappropriate MV sensor-driven rate when MV is programmed ON. Program MV off during mechanical ventilation.
- **Electrosurgical cautery** could induce ventricular arrhythmias and/or fibrillation, and may cause asynchronous or inhibited pacemaker operation. If use of electrocautery is necessary, the current path (electrode tip to ground plate) should be kept as far away from the pacemaker and leads as possible, and the output amplitude of the pacemaker should be programmed to the 5-V setting, or greater.
- **RF ablation** may cause asynchronous or inhibited pacemaker operation, and possible reset of the pacemaker. During RF Ablation, the current path (electrode tip to ground plate) should be kept as far away from the pace-maker and leads as possible, and the output amplitude of the pacemaker should be programmed to the 5-V setting, or greater. Avoid direct contact between the ablation catheter and the implanted lead and pacemaker.
- **Magnetic Resonance Imaging** (MRI) for pacemaker patients has been contraindicated by MRI manufacturers. Clinicians should carefully weigh the decision to use MRI with pacemaker patients.
  - Magnetic and radio-frequency fields produced by MRI may increase ventricular pacing beyond the rate limit, result in total inhibition of pacing output, result in pacing at random rates, or result in asynchronous pacing.
  - Magnetic fields may activate magnet mode operation and cause asynchronous pacing.
  - MRI can irreversibly damage the pacemaker.
  - Pacemaker patients treated with MRI should be closely monitored and programmed parameters should be verified upon cessation of MRI.
- **Lithotripsy** can damage the pacemaker. If lithotripsy must be used, do not focus near the pacemaker site.
- **External defibrillation** may damage the pacemaker. Attempt to minimize the current flowing through the pacemaker and lead system by following these precautions:
  - Position defibrillation paddles as far from the pacemaker as possible and perpendicular to the implanted pacemaker/lead system.
  - Use the lowest clinically appropriate energy output (watt seconds). Protective thyristors help shield pacemaker circuitry from electrical damage during external

defibrillation procedures up to 360 watt-seconds. However, the precautionary measures listed in Chapter 3, External De-fibrillation Protection section, should be implemented.

- **Transcutaneous Electrical Nerve Stimulation** (TENS) may interfere with pacemaker function. If necessary, the following measures may reduce interference:
  - Place the TENS electrodes as close to each other as possible.
  - Place the TENS electrodes as far from the pacemaker/lead system as possible.
  - Monitor cardiac activity during TENS use.
- **Diagnostic x-ray and fluoroscopic radiation** should not affect the pacemaker. However, high radiation sources such as cobalt 60 or gamma rays should not be directed at the pacemaker. If a patient requires radiation therapy in the vicinity of the implanted pacemaker, place lead shielding over the implant site as a precaution against radiation damage.

Home and Occupational Environments

Patients should be advised of the following potential sources of EMI:

- **High voltage power transmission lines** may generate enough EMI to interfere with pulse generator operation if approached too closely.
- **Communication equipment** such as microwave transmitters, linear power amplifiers, or high-power amateur transmitters may generate enough EMI to interfere with pulse generator operation if approached too closely.
- **Commercial electrical equipment** such as arc welders, induction furnaces, or resistance welders may generate enough EMI to interfere with pulse generator operation if approached too closely.
- **EAS equipment** such as retail theft prevention systems may interact with pulse generators. Patients should be advised to walk directly through and not to remain near an EAS system longer than is necessary.
- **Home appliances** which are in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There are reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site.
- **Cellular Phones**. Patients having an implanted pacemaker who operate a cellular phone should observe the following precautions:
  - Maintain a minimum separation of 6 inches (15 cm) between a handheld personal cellular phone and the implanted device. Portable and mobile cellular phones generally transmit at higher power levels compared to handheld models. For phones transmitting above 3 watts, maintain a minimum separation of 12 inches (30 cm) between the antenna and the implanted device.
  - Hold the phone to the ear opposite the side of the implanted device. Patients should not carry the phone in a breast pocket or on a belt over or within 6 inches (15 cm) of the implanted device as some phones emit signals when they are turned ON but not in use (ie, in the listen or standby mode). Store the phone in a location opposite the side of the implant site.

Explanted Pacemakers

- Do not incinerate pacemakers, because they can explode if subjected to incineration or cremation temperatures; be sure that the pacemaker is ex-planted before a deceased patient is cremated.
- Return all explanted pacemakers and leads to Guidant for analysis and disposal. Examination of explanted devices can provide information for continued improvement in device reliability and will permit calculation of any warranty replacement credit due.

- Do not implant an explanted pacemaker in another patient as sterility, functionality, and reliability cannot be insured.

Adverse Events

A total of 130 PULSAR Max devices were evaluated in a clinical study. The patient population included 81 males and 49 females with a mean age of 67.5 years. Total cumulative implant duration was 754 device months, with a mean implant duration of 5.8 months (ranging from 0.1 to 7.2 months).

During the clinical study there were 2 patient deaths, which were reviewed and determined to be non-device related. One death was classified as cardiac/ pump failure and ischemia and the second was classified as cardiac/ arrhythmic.

One device was explanted as part of a system revision.

Sustained high rate pacing occurred in some patients post-implant. In all cases it was mitigated by programming the minute ventilation sensor response factor to a lower setting or by establishing a new sensor baseline using the 4-ON recalibration feature (see WARNINGS).

Observed Adverse Events

Table 1 reports the number of adverse events, percent of patients who experienced at least one adverse event, and the number of events per device-year in descending order of frequency.

Table 1. Adverse Events Reported—All Patients.
(N = 130 devices in 130 patients, 62.8 device-years)

Adverse Events Reported	# of Events	% of Patients	Events per Device-Year
Any adverse event	38	29.2	0.605
High Rate Pacing	10	7.7	0.159
Lead Dislodgement / Placement Difficulty	9	6.9	0.143
Change in physical status	8	6.2	0.127
Chest pain	8	6.2	0.127
Pneumothorax	3	2.3	0.048
Infection	2	1.5	0.032
Cardiac arrest	2	1.5	0.032
Brady capture – None or loss of capture	1	0.8	0.016
Dizziness – cause undetermined	1	0.8	0.016
Hypotension	1	0.8	0.016
Oversensing	1	0.8	0.016
Palpitations	1	0.8	0.016
Pacemaker-mediated tachycardia (PMT)	1	0.8	0.016
Pulmonary embolism	1	0.8	0.016
Software error message	1	0.8	0.016
Syncope	1	0.8	0.016
Acute elevated thresholds	1	0.8	0.016
Trending related	1	0.8	0.016
Undersensing	1	0.8	0.016

Potential Adverse Events

Historically reported potential physical effects from implantation of a pacemaker are listed below in alphabetical order:

- Cardiac perforation
- Cardiac tamponade
- Elevated thresholds
- Erosion through the skin
- Fibrotic tissue formation
- Foreign body rejection Phenomena
- Transvenous lead-related thrombosis
- Hematoma/seroma
- Local tissue reaction
- Myopotential sensing
- Nerve and muscle stimulation
- Pacemaker migration
- Patient death

In addition, electronic devices such as pacemakers are subject to random component failures that cannot be predicted and can lead to failure to pace.

Clinical Studies

The exercise rate response of PULSAR Max pacemaker was evaluated in a multi-center (13 US centers and 15 European) prospective study. Patients were randomized to either Minute Ventilation only and Blended sensor Modes (accelerometer + minute ventilation) for the first month post-implant.

Methods: Rate response was evaluated using system diagnostic outputs during pre-discharge submaximal exercise using a low-intensity treadmill exercise (LITE) protocol for sensor optimization and 24-hour Holter monitoring. Chronotropic Assessment Exercise Protocol (CAEP) treadmill data were used to assess sensor-indicated rates at each exercise stage of the CAEP protocol using repeated treadmill tests (MV only and Blended sensor mode) at the 1 month follow-up.

Description of Patients and Implant Duration: A total of 130 patients were implanted with the dual chamber (DR) PULSAR Max pacemaker Model 1270 in a controlled, prospective study. In these patients, 110 CAEPS were performed (n=56 blended, n=54 MV only), and data were available for 96 of these (see table 5). The average implant duration was 5.8 months with a maximum implant duration of 7.2 months and a total cumulative implant experience of 754 device months. The mean age of patients implanted with this device was 67.5 years, with a standard deviation of 13.2 years.

Table 2 provides a summary of patient characteristics. Table 3 lists the patient arrhythmia history.

Table 2. Patient Population Characteristics

Characteristic	Number
Age at Implant (years)	
Minimum	18.2
Maximum	92.2
Mean	67.5
Standard Deviation	13.2
Gender (# of patients, %)	
Male	81 (62.3%)
Female	49 (37.7%)

Table 3. Patient Arrhythmia History

Arrhythmias*	Number of subjects
Sinus Bradycardia	40
Sinus Arrhythmia	1
Paroxysmal Atrial Fibrillation	27
Atrial Fibrillation (AF) (Chronic)	1
Atrial Flutter	4
PSVT	3
PAT	5
Sinus Arrest	6
Sinus Node Dysfunction (Brady-Tachy Synchrony)	21
1st - Degree AV Heart Block	19
2nd - Degree AV Block (Mobitz 1)	6
2nd - Degree AV Block (Mobitz 11)	18
3rd - Degree AV Block	33
Left Bundle Branch Block	6
Right Bundle Branch Block	11
Arrhythmia Resulting from Ablation	4
Intraventricular Conduction Delay	1
Other	23

(*Numbers may not be summed as some patients may be reported in more than one category.)

Table 4 below summarizes the programmed parameters for patients who performed CAEP exercise testing.

Table 4. Programmed Parameters During CAEP Testing
(n=55 patients)

Brady Parameter	Mean	Standard Deviation	Minimum	Maximum
Lower Rate Limit	64	6.5	55	80
Maximum Sensor Rate	151	16.0	100	185
MV Rate Response Factor	5	1.7	3	11

The Expected Heart Rate (EHR) and the Sensor Indicated Rate (SIR) at each stage of exercise were used to generate a slope of response to graded exercise testing (CAEP), using the Wilkoff model. Sensor indicated rates of MV and Blended sensor were measured in repeated (two) identical CAEP treadmill tests with MV or Blended sensor turned on. The EHR slope and the observed SIR slope responses were then compared. A slope of 1.0 was the expected response.

Overall device safety and appropriate performance of the enhancement features were evaluated when the device was assigned to either the MV-only or Blended sensor mode during the follow-up period.

Results: Figure 1 shows the relationship between expected heart rates and the observed sensor-indicated rates for all patients undergoing exercise testing in blended sensor mode. The analysis was based on a normalized interval average with the corresponding 95% confidence intervals, for all patients completing at least four stages of exercise.

Figure 1. Sensor-indicated rate (SIR) vs expected rate during CAEP
(All patients completing at least four stages of exercise, blended sensor only (n=46, at 1 month))

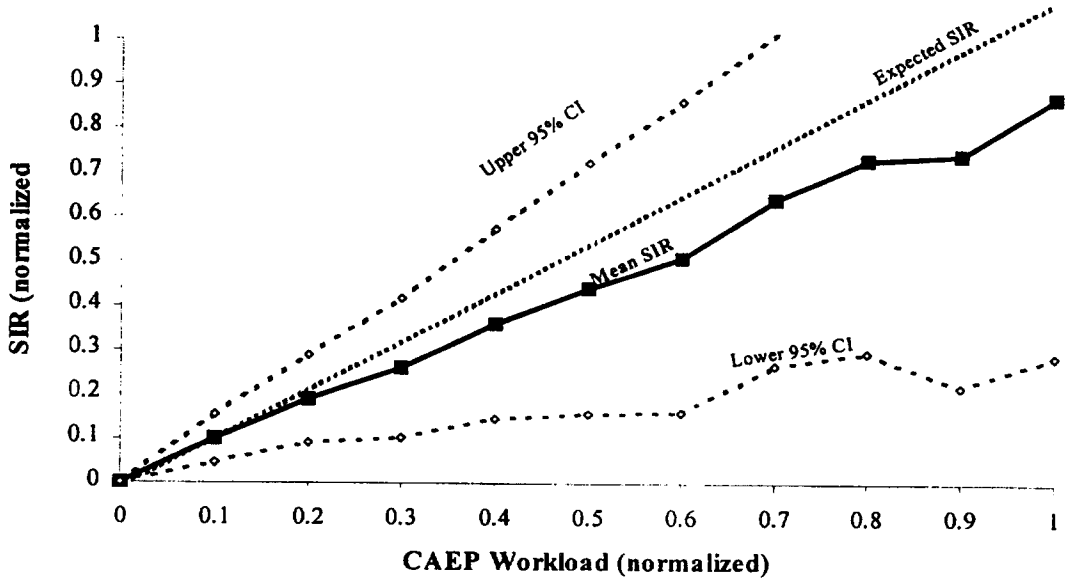

Table 5 shows the summary statistics for exercise testing in Blended sensor and MV-only modes

Table 5 Results of Exercise Testing – Total Clinical Population
(n=110 CAEPS total)

Population	n (% of pts)	Slope mean [95% CI]
Blended	51 (91%)	0.81 [0.73, 0.89]
MV Only	45 (83%)	0.83 [0.74, 0.92]

Conclusion: The results met the acceptance criteria as defined in the PDP protocol Primary Efficacy Endpoint (95% confidence interval of the slope completely contained within [0.65, 1.35]). These results demonstrate that the sensor indicated rates in the overall population are proportional to increasing workload in a linear fashion as seen in the normal heart rate to workload relationship.

Subanalysis (Population Reaching Maximal Exertion): Figure 2 below summarizes the results from a subgroup of patients who reached maximal exertion at their final stage of CAEP exercise. This subgroup includes those subjects who did not terminate exercise testing prematurely due to an abnormal response (eg., angina, drop in blood pressure) as defined by the American College of Sports Medicine[1].

Figure 2. Sensor-indicated rate (SIR) vs expected rate during CAEP (1 month).

All patients who exercised to their age-predicted maximal heart rate (n=31)

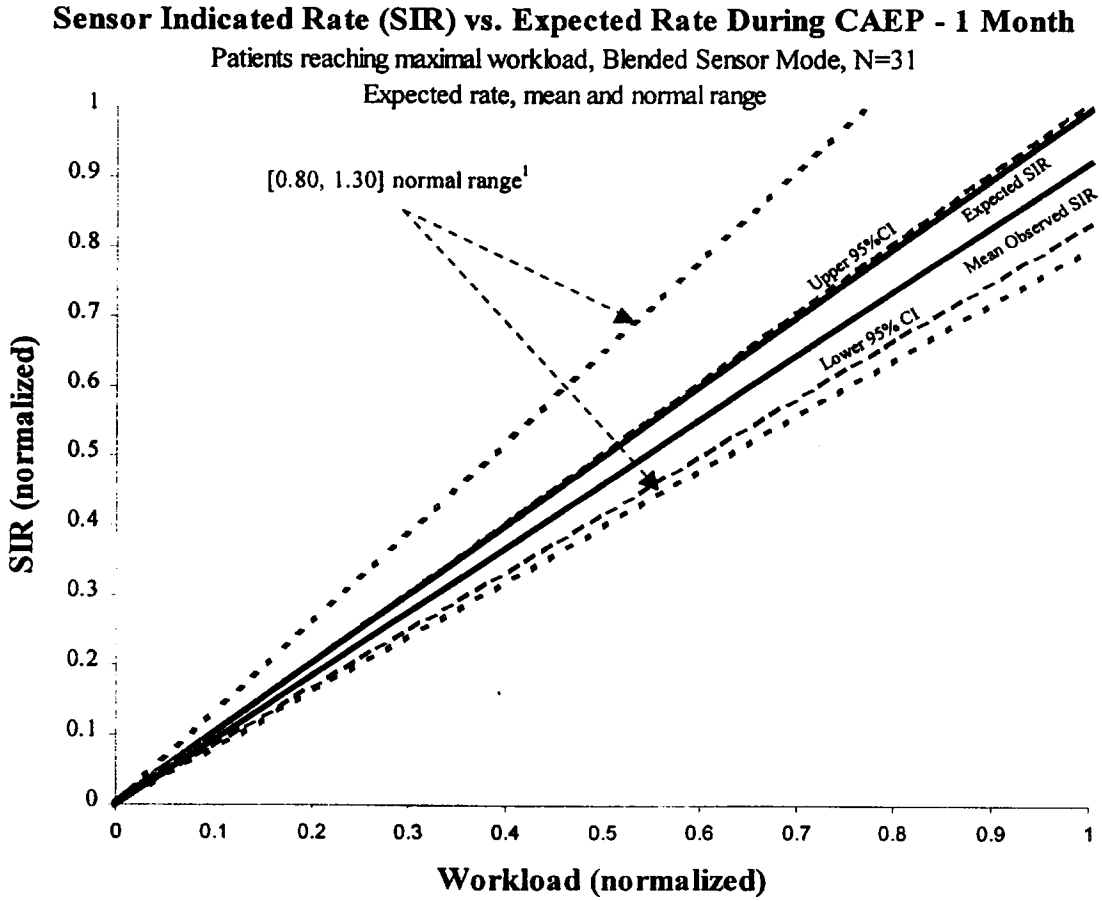

Table 6 shows the summary statistics for exercise testing in Blended sensor and MV-only modes

Table 6. Results of Exercise Testing – Population Reaching Maximal Exertion

Population	n (% of pts)	Slope mean [95% CI]
Blended	31 (55%)	0.92 [0.83, 1.01]
MV Only	29 (54%)	0.97 [0.89, 1.05]

[1] ACSM Guidelines for Exercise Testing and Prescriptions. 4th ed. Lea & Febiger Philadelphia,1991.

The subset of the patients who exercised to their age predicted maximal heart rate demonstrated a 95% confidence interval of the slope that falls within the expected normal range as defined by Wilkoff [0.80, 1.30][2].

Patient Counseling Information

Physicians should consider the following points in counseling the patient about this device:

- Signs and symptoms of infection
- Symptoms that should be reported (e.g. sustained high rate pacing requiring reprogramming)
- Activity restrictions (if applicable)
- Minimum heart rate (lower rate limit of the pacemaker)
- Frequency of follow-up
- MV sensor adaptation process and symptoms of high rate pacing

Patient Manual

A copy of the patient manual is packaged with each device. It contains information for the patient, patient's relatives, and other interested people. Discuss the information in the manual with concerned individuals both before and after pacemaker implantation so they are fully familiar with operation of the device. For additional copies of the patient manual, contact the nearest Guidant sales representative or contact Guidant at the address on the back cover of this manual.

Patient ID Card

A temporary patient ID card is packaged with each device. A permanent ID card will be sent to the patient four to six weeks after the implant form is received by Guidant. The patient should be advised to carry the Patient ID card at all times.

[2] Wilkoff et. al. A mathematical model of the cardiac chronotropic response to exercise. Journal of Electrophysiology 1989;3:176-180.